K132457

FEB 2 1 2014

喬陽醫學科技
BIOCARE ASIA CO., LTD.

510(k) Summary

Jan.8 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K132457

1. Submitter's Name: BioCare Asia Co., LTD

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2. Device Name and Classification

Trade name: FORA Diamond Nexus Mini Infrared Forehead Thermometer

Common name: Clinical electronic thermometer

Regulation section: 21 CFR 880.2910

Classification Code: FLL, Clinical electronic thermometer

Classification Panel: General Hospital (80)

Device Classification: Class II

3. Predicate Device

The predicate device is URIGHT TD-1240 Thermometer (K113159) marketed by TaiDoc Technology Corporation.

4. Device Description

FORA Diamond Nexus Mini Infrared Forehead Thermometer is characterized by measuring human body temperature from the surface of human skin. It utilizes infrared

technology to measure infrared energy emitted from the skin surface when making a temperature measurement.

5. Intended Use

FORA Diamond Nexus Mini Thermometer is intended for the intermittent measurement and monitoring of human body temperature from forehead measurement at home.

6. Comparison with predicate:

FORA Diamond Nexus Mini Infrared Forehead Thermometer has the following similarities to the predicate device:

- Same Indications for use.
- Same operating principle and fundamental scientific technology.
- Incorporates the same materials.
- Same shelf life.
- Packaged using the same materials.
- Has the same memory storage capacity.

The FORA Diamond Nexus Mini Infrared Forehead Thermometer has the following dissimilarity to the predicate device:

Item	FORA Diamond Nexus Mini Infrared Forehead Thermometer	U-RIGHT TD-1240 Thermometer (k113159)
Body Measuring Range	89.6°F to 109.4°F (32°C to 43°C).	73.4°F to 111.2°F
Operating temperature	60.8°F to 104°F (16°C to 40°C).	50°F to 104°F
Storage temperature range	-13°F to 131°F (-25°C to 55°C)	-4°F to 140°F
power down time	15 seconds	3 minutes

battery type	One 3V CR2032 lithium battery	1.5V AA
LCD Backlight	white	blue

The differences between the two devices list as: display, parameters and appearance. There are no significant differences that affect the safety and effectiveness. Therefore, BioCare Asia FORA Diamond Nexus Mini Infrared Forehead Thermometer is substantially equivalent to the legally marketed device U-RIGHT TD-1240 Thermometer manufactured by TaiDoc Technology Corporation, K113159.

7. Performance Characteristics: (Non-clinical testing data)

The FORA Diamond Nexus Mini Infrared Forehead Thermometer was validated by the tests According to ASTM E1965-98 standard and met the requirements of EN12470-5:2000 standard.

A brief description for each test was given in this section. Following table lists items of tests, related standard complied and acceptance criteria.

Item	Standard complied	Acceptance criteria	Attachment
Clinical accuracy	ASTM E 1965-98 EN-12470-5	±0.3℃(±0.5°F)	23
Laboratory accuracy	ASTM E 1965-98 EN-12470-5	±0.3℃(±0.5°F)	23
Shock test	ASTM E 1965-98	±0.3℃ (±0.5°F)	25
Storage environment test	ASTM E 1965-98	±0.3℃ (±0.5°F)	26
Displayed temperature range	ASTM E 1965-98	±0.3°C (±0.5°F)	27
Operating condition range 36-39℃(96.8-102.2°F)	ASTM E 1965-98 EN-12470-5	±0.2°C (±0.4°F)	28

Operating condition range <36℃(96.8°F) or >39℃(102.2°F)	ASTM E 1965-98 EN-12470-5	±0.3°C (±0.5°F)	28
Safety	IEC 60601-1	Evaluated by SGS	19
Electromagnetic compatibility (EMC)	IEC 60601-1-2	Evaluated by SGS	22
Home Healthcare Equipment	IEC 60601-1-11	Evaluated by SGS	20

8. Performance Characteristics: (Clinical testing data)

Two kind of errors were represented in clinical accuracy: clinical bias and clinical repeatability. Following table is the pooled clinical bias and its standard deviation of 1267.

Device	Sample size	The pooled clinical bias	Bias+1.96 SD	Bias-1.96 SD	Uncertainty
1267	120	-0.08	0.44	-0.60	0.02

The following show the pooled clinical repeatability of 1267.

Device	Sample size	The pooled clinical bias
1267	120	0.11

7. Test Principle:

The thermometer measures temperature by reading infrared radiation emitting from the skin and converts it into a temperature value.

8. Conclusions

Based on the information provided in this submission, the FORA Diamond Nexus Mini Infrared Forehead Thermometer is substantially equivalent to the predicate U-RIGHT 1240 Thermometer, model TD-1240.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

BioCare Asia Corporation, Limited
Ms. Shuchi Chang
Administrator, R&D Department
No.260, Mayun Road
New District Suzhou, Jiangsu 215129
P.R. China

Re: K132457
Trade/Device Name: FORA Diamond Nexus Mini Infrared Forehead Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 15, 2014
Received: January 17, 2014

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132457

Device Name
FORA Diamond Nexus Mini Infrared Forehead Thermometer

Indications for Use *(Describe)*

FORA Diamond Nexus Mini Infrared Forehead Thermometer is intended for the intermittent measurement and monitoring of human body temperature from forehead measurement at home.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman
Date: 2014.02.19 14:49:37 -05'00'

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